REMARKS:

Claims 1, 2, 5-8 and 12-14 are in the case and presented for consideration.

The specification has been amended to refer to the U.S. patent 6,733,292 which was granted on the parent application and to correct an awkward section of paragraph [0015].

Turning to the Office Action, the claims have been renumbered according to the Examiner's observation and the lack of a claim 11 originally.

Claim 1, the only independent claim, has also been amended to include various features and relationships which are believed to define a patentable combination over the prior art. Specifically claim 1 now requires the presence of the polished cylindrical collar 21 above the textured cylindrical neck 19, and the tapered lower portion 12 to be axially longer than upper portion 18 (as supported by all of the drawings originally filed). Claim 1 also includes the platform 24 and the fact that the platform includes an upper, outer polished surface 27 that is contiguous with the cylindrical outer surface of the polished collar 21 (see paragraph [0040] of the specification).

Returning to the Office Action, the Examiner has rejected claims 1-5 and 9-13 as being obvious from a combination of the U.S. patents to Day, Somborac and Wimmer (respectively U.S. patents 5,947,735; 5,636,989 and 5,302,126).

To help the Examiner better understand a structure manufactured in accordance with the present invention, attached please find a digital photograph on a greatly enlarged scale of an implant constructed according to the invention. The only difference is that the cylindrical textured neck 19 has a smaller diameter than the polished collar 21 with its contiguous polished outer surface 27 of the platform.

Attached also please find an article by Scipioni, et al, which will be referred to later in these remarks.

In addition, attached to this amendment is a Terminal Disclaimer disclaiming the terminal portion of the present application which would extend beyond the full term of U.S. patent 6,733,292 as well as the additional fee of $65.00 in excess of the extension charges for a small entity for recording this Terminal Disclaimer.

Turning first to the existence and placement of the cylindrical polished collar:

Polished Collar

The person of ordinary skill in this art, as that person is contemplated by 35 U.S.C. 103, would not "...modify Day to include a polished collar as shown by Somborac in order to better hold the anchor within the tissue." (Office Action of 08/11/2004, page 2, line 16-18), since that is *not* the purpose of the polished collar of the present invention.

The basis of this holding may have been the purpose declared by Somborac in its teaching of the function of this polished part of its implant at column 7, lines 17 through 21 of Somborac. Further at column 7, lines 30 through 35 of Somborac it is taught that the cortical bone "...subsides away from the smooth biocompatible surface of the emergent portion 22." Somborac teaches that the machine polished portion of what it calls the "fourth taper" (number 22), is not a part of the collar but is a "smooth-wall portion" of the body of the implant and is necessary to "avoid gum and bone infection..." (column 3, line 59). Number 24 in Fig. 1of Somborac is in fact the collar which is called the part of the "coronal portion 12" (column 4, line 6), and it is not specified to be rough or smooth. Its shape is a combination of tapers. Number 22, the polished portion is shown in Fig. 8 of

Somborac to be placed in such a way as to be forcefully wedged into cortical bone (90B in Fig. 8) and as such is not appropriately termed a "collar." Rather it acts as a part of the body of the implant that is wedged into the cortical bone.

The polished portion of the cervical part of an implant commonly termed the "collar" is designed to be supra-crestal to the cortical bone and to present a smooth surface within the gingival sulcus. The claims of the present application call for a polished collar which is placed *above* the cortical bone engaging textured neck 19 and does not depend upon unpredictable amounts of bone resorption to become an emergent collar, as is the case with the Somborac teaching (see column 7, lines 29-32 and lines 35–39 of Somorac).

Significantly the claimed implant collar is not tapered and exerts no pressure on the adjacent tissues at any time. The claimed placement is meant to present a smooth surfaced collar directly to the healing gingival tissue at the time of insertion and thereby be predictably more compatible with the formation of a natural gingival sulcus insuring optimum cleansability of the collar's surface after healing. The collar is in line with the body of the implant and not tapered in order to avoid the formation of an undercut crevice at the point of emergence, and as such, it does not encourage crestal bone resorption.

The crevice that occurs in the case of Somborac is the result of the inevitable and indeed, according to Somborac, desired resorption of crestal bone (see column 7, lines 17-26 and lines 29-39). Bone resorbs when pressure is exerted upon it. By comparison, the claimed invention greatly diminishes the possibility of gingival or bone infection via the ease with which bacterial plaque growth would be inhibited by oral hygiene procedures as a result of the supra-crestal placement of its collar and the formation of a natural gingival sulcus.

Wedging the tapered collar of an implant into the cortical bone as taught by Somborac ultimately would make that surface less predictably accessible to oral hygiene procedures and more likely to form infrabony defects. Infrabony defects have been notoriously indicted for years in the periodontal-implant literature and in clinical practice to be responsible for the advancement of periodontal and peri-implant bone destruction. The resorptive activity of the crestal (cortical) bone which Somborac seeks, accurately describes the formation of just such undesirable bone defects which is the very opposite of the declared intention by Somborac, i.e. to protect against gum and bone infection. In any case it is considered undesirable to encourage the crestal resorption of peri-implant bone. This is a significant clinical difference between the claimed invention and Somborac with respect to the structure and placement of the polished collar.

Also the person of ordinary skill in this art understands that press fit implants which have been used for years do not need and have not needed to depend upon a wedging action of the neck of the implant for stability.

Implant Taper

The claimed implant also has a cylindrical portion (e.g. at 19 in Fig. 1 of the application) directly below the polished collar, then a taper extending to the apical tip of the claimed implant. The Somborac design has a taper only at the very apical portion of the implant. This is significant in that the Somborac design restricts the width of the alveolar housing (jaw bone width), into which an implant may be placed for most of its length. In the claimed implant anchor, the tapered section of the implant is longer than the upper cylindrical collar and neck. The current application as filed, e.g. in Fig. 1-9, 13 and 14,

clearly shows that the taper begins directly below the short cylindrical "neck" of the implant and extends for a major portion of the body of the implant all the way to the apex. The reason for the taper designed this way is to permit placement of the implant into narrow ridges of resorbed bone so commonly found in edentulous (toothless) areas of the jaw. It also creates an effective means of fitting the body of the implant between the roots of two teeth adjacent an edentulous space (which frequently converge upon each other), while maintaining a more coronal bulk of the implant body for needed support.

This taper also permits a significant advantage when applied in the technique of "Edentulous Ridge Expansion" (see the attached "Bone Regeneration in E.R.E Technique: Histological and Ultrastructural Study of Twenty Cases," Scipioni, Bruschi, Calesini and De Marino, International Journal of Periodontal and Restorative Dentistry, 9:269-277, 1999) since its form permits placement of an implant of this kind in narrow ridges without the necessity of grafting bone to the site.

It has already been successfully applied clinically in cases of normal placement and in cases requiring ridge expansion techniques.

Platform With Contiguous Outer Polished Surface

To even further distinguish the claimed invention over the prior art, claim 1 defines the presence of the platform shown at 24 in Figs. 1 and 2 which includes the upper, outer polished surface 27 that is contiguous with the polished collar 21 of th upper portion 18 of the implant anchor 10.

Day does not include a platform in the sense of the present invention nor an outer polished surface contiguous with any other part of the anchor. Somborac likewise has no

platform or polished surface. A so-called "coronal portion" 12 shown in Fig. 1 of Somborac, includes an outer tapered section 24 which tapers up from the also tapered polished surface 22. Surface 22 is neither cylindrical nor is it contiguous with the outer surface of coronal portion 12 (even assuming this portion is similar to a "platform" of the claimed invention) nor is it disclosed that surface 24 should be polished.

Wimmer includes a structure called a post 40 which engages at the top of the implant anchor and is held by a screw 30 but with no outer polished surface contiguous with an outer polished and cylindrical surface of the implant anchor. Carmichael at Fig. 7 shows an upper portion attached to an anchor that might qualify as the platform of the claimed invention but again with no outer polished surface contiguous with the cylindrical outer polished surface of the anchor. Niznick is likewise missing this feature so that no combination of the references nor any other references of the prior art are believed sufficient to render claim 1 obvious.

The remaining claims are believed to distinguish the invention even further from the prior art so that the application and claims are believed now to be in condition for allowance and favorable action is respectfully requested.

The Examiner is respectfully urged to telephone the undersigned to discuss this case and reach a conclusion to the prosecution thereof.

Respectfully submitted,

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The Edentulous Ridge Expansion Technique: A Five-Year Study

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*Giovanni B. Bruschi, MD, DDS**
*Gaetano Calesini, MD, DDS**

This study presents the clinical results of a surgical technique that expands a narrow ridge when its orofacial width precludes the placement of dental implants. In 170 people, 329 implants were placed in sites needing ridge enlargement using the edentulous ridge expansion procedure. This technique involves a partial-thickness flap, crestal and vertical intraosseous incisions into the ridge, and buccal displacement of the buccal cortical plate, including a portion of the underlying spongiosa. Implants were placed in the expanded ridge and allowed to heal for 4 to 5 months. When indicated, the implants were exposed during a second-stage surgery to allow visualization of the implant site. Occlusal loading was applied during the following 3 to 5 months by provisional prostheses. The final phase was the placement of the permanent prostheses. The results yielded a success rate of 98.8%. (Int J Periodont Rest Dent 1994;14:451–459)

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Orofacial width of bone that is too narrow to permit the total inclusion of an implant within the bony housing is a common problem in the placement of dental implants. This is especially limiting in the maxillary arch when postextraction collapse of the labial plate of bone necessitates a palatally displaced implant. This generally creates functional difficulties related to opposing teeth.

Esthetics also suffer if the edentulous ridge apical to the emergence profile of the crown is concave. This is of particular importance in the maxillary anterior region. Also, if the facial portion of a crown overlaps the ridge in an attempt to maintain proper alignment with the adjacent teeth, then the patient's oral hygiene may be severely compromised.

All of the above considerations led to the development of a technique that, in effect, expands the edentulous ridge buccally in a highly predictable way. This study deals

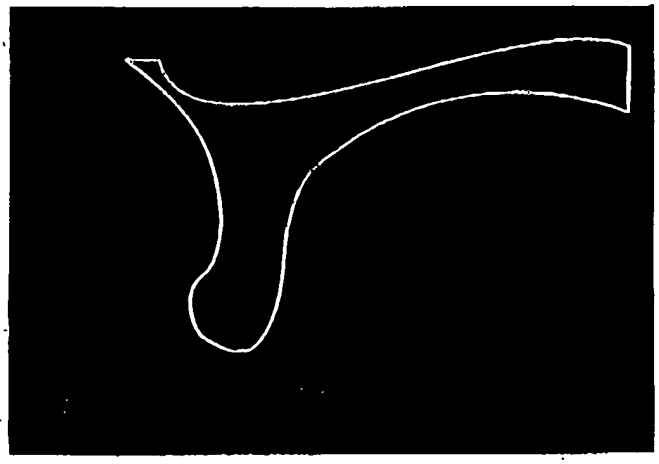


Fig 1a A crestal incision is made.

Fig 1b Partial-thickness buccal and lingual flaps are raised, followed by two vertical incisions defining the surgical area.

with situations in which the ridge is so narrow that implant placement using the traditional technique is impossible. The present investigation was undertaken to assess the effectiveness of the technique called edentulous ridge expansion (ERE) for implant placement.

Method and materials

In 170 individuals, 329 implants were placed in alveolar ridges that were too narrow orofacially to permit traditional implant installation. The ERE technique was used in all cases.

All patients were premedicated 1 hour before surgery with an antibiotic (Ciproxin, Bayer), 1g per day, and an anti-inflammatory agent (Naprosyn, Recordati), 1.5 g per day. Two types of implants were included in this study: Al_2O_3 implants (Tübingen and Monaco versions,Friatec) and IMZ implants (Friatec).

Using the ERE technique, a palatal incision in crestal direction was made, and partial-thickness buccal and lingual flaps were raised (Figs 1a and 1b), followed, when necessary, by two vertical releasing incisions defining the surgical area. After the flaps were reflected, two transperiosteal incisions were made into the bone parallel to the releasing incisions (Figs 1c and 1d); two vertical grooves were formed by the penetration of the buccal cortical plate of the bone. The crestal incision was continued into the bone (Fig 1e) so that an intraosseous groove was formed with a #64 Beaver blade. This groove was continued apically (Figs 1f and 1g) and, when sufficient depth was reached, the buccal plate was slowly dislocated in a facial direction (Figs 1h and 1i). Care must be taken to maintain a zone of spongiosa beneath the cortical plate so that there is a minimum overall thickness of approximately 1.5 mm.[1] The blood supply on the facial aspect of the displaced buccal plate must also be maintained by safeguarding the

Figs 1c and 1d *Two transperiosteal incisions are made in the bone parallel to the releasing incisions.*

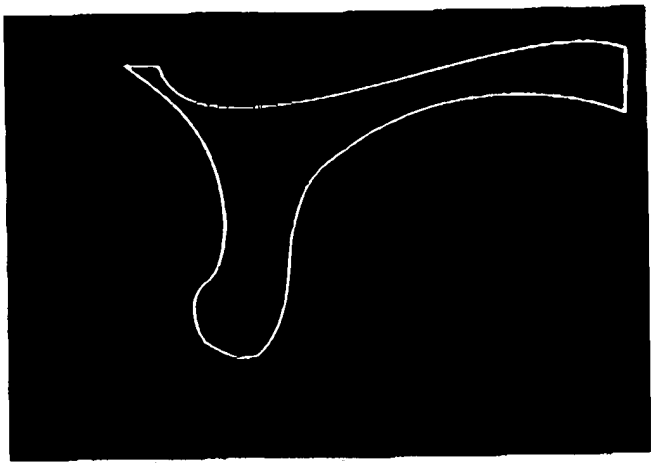
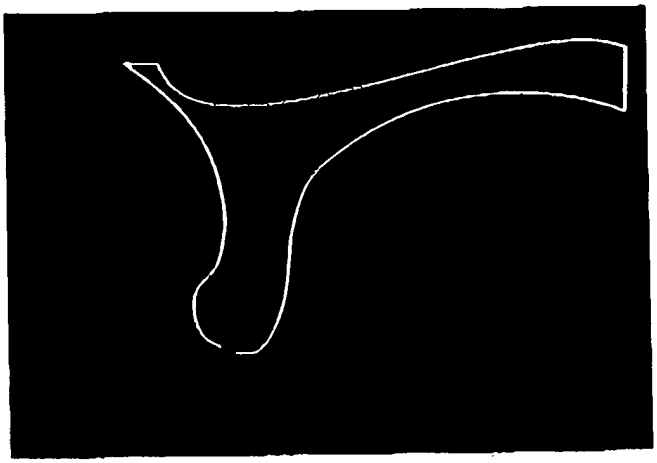
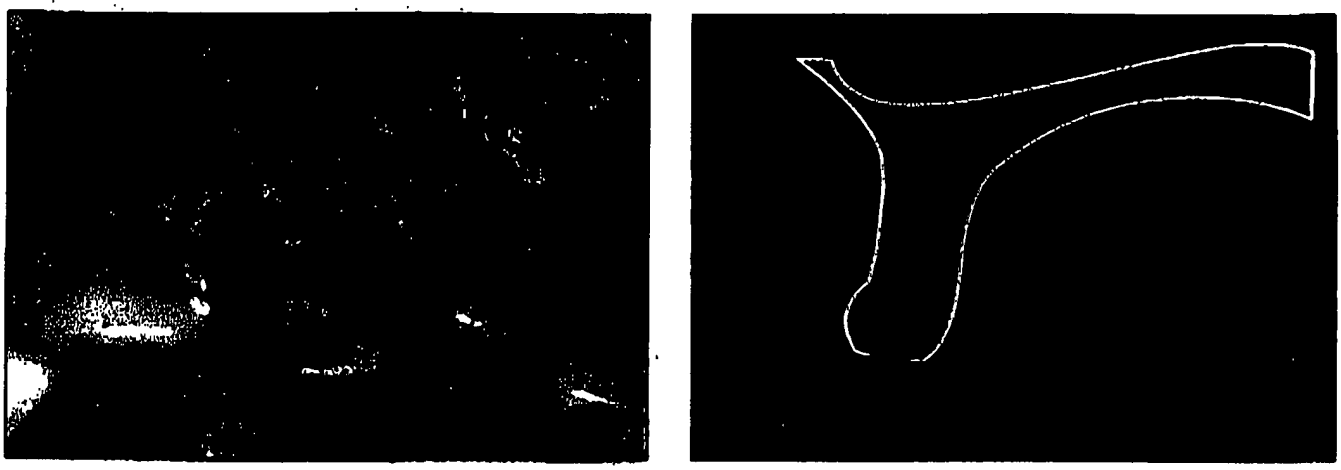


Fig 1e (right) *The crestal incision is continued into the bone.*



Figs 1f and 1g *The groove is continued apically.*



Figs 1h and 1i The buccal plate is slowly dislocated in a facial direction.

integrity of the periosteum (Odrich RB, personal communication, 1992).[2-9]

Implants were placed within the confines of the newly created space (Figs 1j to 1l) and the flaps were closed (Fig 1m). Antibiotic and anti-inflammatory medication was continued for a total of 3 days. After 4 to 5 months, the second phase of surgical exposure was carried out in all cases except those using the Tübingen implants. A provisional partial denture was kept in place for 3 to 5 months, at which time the final prosthesis was placed.

The standard of success for implant function as established by Albrektsson et al[1] was chosen because it is the ultimate fate of the "loaded" implant rather than the ridge expansion that is the more significant factor in this study. Implants were included in the study from the day of insertion and were considered successful after 5 months of final prosthetic reconstruction and occlusal loading. It should be noted that, prior to the final prosthetic insertion, each implant reported here had been in place at least 1 year before being included in this analysis.

The Al_2O_3 implants are most suited for use in the maxillary anterior region as single elements and were used accordingly. The IMZ implants were used for the reconstruction of large edentulous surfaces. In all, 96 Al_2O_3 implants and 233 IMZ implants were inserted using the ERE technique.

Fig 1j

Fig 1k

Figs 1j to 1l Implants are placed within the confines of the newly created space.

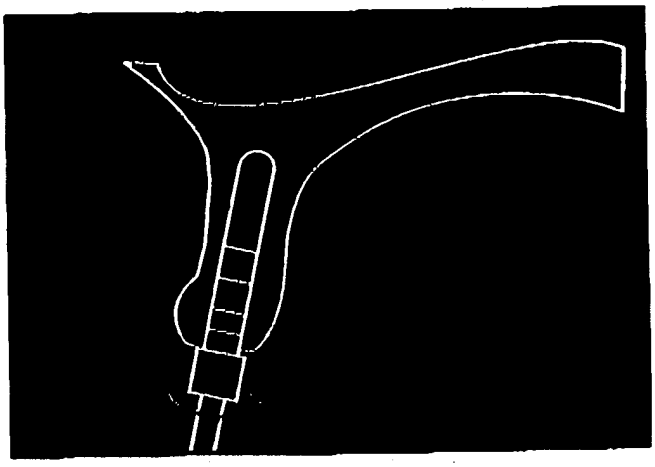


Fig 1l

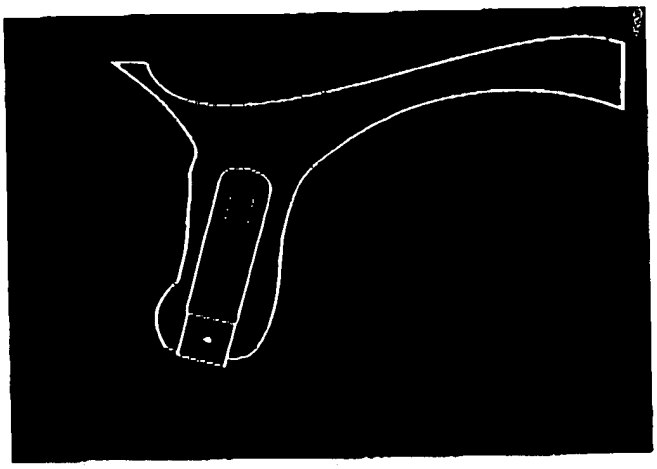


Fig 1m The flaps are closed.

Table 1 Success rate for Tübingen implants

Year	No. of implants	No. of patients	No. of failures
1986	9	6	0
1987	13	12	2*
1988	11	8	0
1989	38	35	3**
1990	25	22	1***
Total	96	85	6****

*Fractured implant placed in 1987.
**Fractured implants placed in 1987 and 1989.
***Fractured implant placed in1989.
****Two lost implants, four fractured implants.

Table 2 Success rate for IMZ implants

Year	No. of implants	No. of patients	No. of failures
1988	26	11	0
1989	68	26	0
1990	139	48	2*
Total	233	85	2

*Failed implant placed in 1989.

Results

Results of this study are shown in Tables 1 and 2. There was an 88.5% success rate for the Tübingen implants (see Table 1) using the ERE technique. All except nine implants were placed in the region of the maxillary incisors. The IMZ implants yielded a 99.0% success rate (see Table 2). The total success rate for both types of implants using the ERE technique was 98.5%, discounting the four fractured fixtures (see Table 1).

Discussion

The ERE technique permits placement of implants in sites that otherwise do not provide enough bone to permit osseointegration. By expanding the buccal cortical plate, the buccal concavity generally encountered in postextraction ridges is greatly reduced, thus permitting implant placement, proper emergence profile, and effective oral hygiene.

An essential feature of the ERE technique is the partial-thickness flap. In such procedures, the blood supply must be kept intact on the facial aspects of radicular bone to ensure optimal healing and preservation of the very thin bone that covers root prominences (Odrich RB, personal communication, 1992). The

Fig 2a Edentulous ridge at area of teeth 8 to 10, which were lost 20 years previously in an automobile accident. Note lack of dimension to arch form.

Fig 2b Probe maintaining displacement of labial plate of bone while further ridge expansion is effected with elevator.

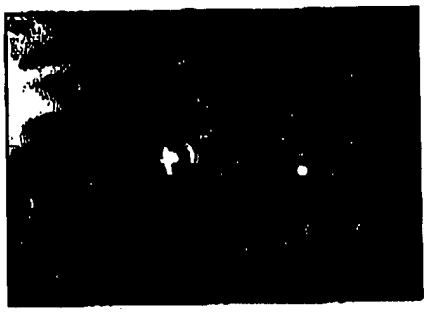


Fig 2c Two probes placed in implant sites.

partial-thickness flap also aids in immobilization of the displaced buccal cortical plate.

When using the ERE technique, the integrity of the periosteum must be maintained so that fenestrations, dehiscences, or necrosis of the buccal plate are avoided during the placement and healing phase of osseointegrated implants. It is thus necessary to maintain buccal cortical bone and spongiosa at a minimum thickness of not less than 1.5 mm. The rates of revascularization of cortical bone (0.005 mm per day) and medullary bone (0.500 mm per day) are thereby assured.[10,12-13]

In this study, the consistent total bone fill achieved in each case was remarkable. It should be noted that this was accomplished without the use of a membrane and, thus, without its inherent risk of postoperative infection. Over the years, other investigators[14-18] have presented a variety of surgical solutions to the problem of narrow alveolar ridges and implant placement. Streckbein and Woltge,[14] and Koury[16] used bone grafts to increase bone support. Osborn,[16] and Nentwig and Kniha[17] suggested the use of hydroxyapatite. A recent investigation by Nyman et al[18] used guided tissue regeneration materials and techniques to attempt a solution.

In this study, the two failures of Al_2O_3 implants occurred in the same patient, an 18-year-old woman who had lost all four maxillary incisors in an automobile accident. This was one of the first cases treated with the ERE technique in 1986. The failure was due to a fenestration of the palatal bone surface, probably the result of an erroneous evaluation of the bone thickness.

Four of the failures noted in Table 1 were the result of implant fracture, as indicated. One fracture was due to a motorcycle accident; the remaining three were attributable to occlusal overload.

The two failed IMZ implants are still in function, but are considered failures because they have lost substantial bony support: one has lost crestal bone for 10% to 15% of its length, the other for approximately 40% of its length. It is interesting to note that these failing implants occurred in the same patient, aged 43 years, who was heavily medicated with anticoagulant therapy for pre-existing cardiac pathosis.

The healing period for implants inserted with the ERE technique appears to be the same as for other implants, although it is recommended that the provisional prosthetic phase be extended for more than the usual 2 months. Figures 2a to 2j are representative of a case using the ERE technique.

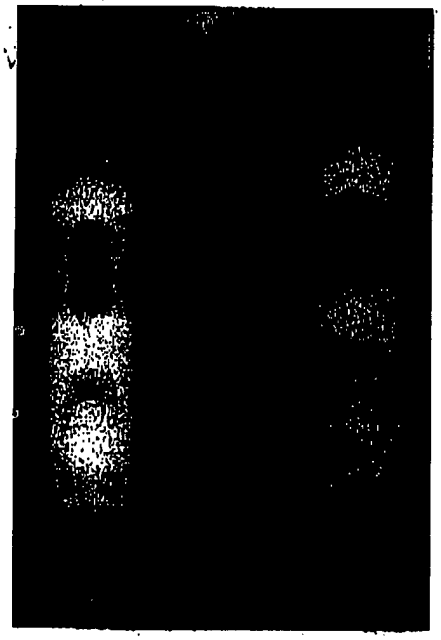


Fig 2d (left) *Radiograph of both implants at time of insertion.*

Fig 2e (right) *Flap closure with subperiosteal sutures.*

Fig 2f (right) *Ridge at 6 months postinsertion (second stage).*

Fig 2g (left) *Healing abutments in place at second stage. Note total bone fill and expansion of ridge labially.*

Fig 2h (right) *Healing 1 month after second stage procedure. Labial flap is positioned apically; note labial expansion of ridge profile.*

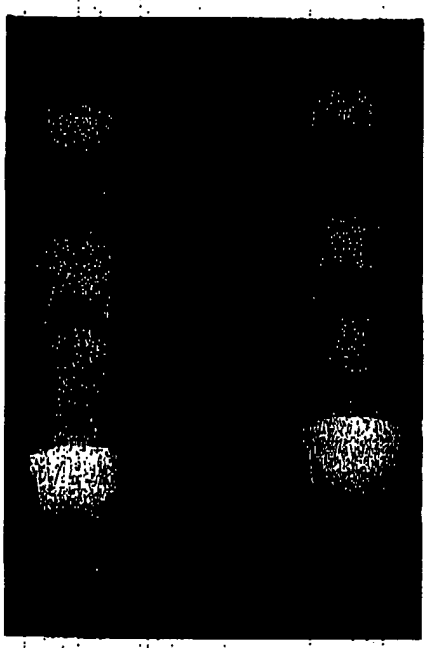


Fig 2i (left) *Radiograph of implants 11 months after occlusal load with porcelain crowns.*

Fig 2j (right) *Aspect of the alveolar crest reconstructed with its physiologic curvature and with distinct radicular prominences around the implants after 11 months of occlusal load.*

Conclusion

The 98.5% total success rate and the rapidity of total bone fill are encouraging signs that the ERE technique offers a potential solution to the problem of placing implants in narrow ridge sites.

Acknowledgments

The authors wish to thank Dr Ronald B. Odrich for his translation of the material and Dr Johanna Odrich for her editorial assistance.

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